IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION

United States, *ex rel.* JOHN DOE, BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA, and THE STATE OF NORTH CAROLINA,

Plaintiffs,

v.

HARI P. SAINI, M.D.; CAROLINA HEART AND LEG CENTER, P.A., a North Carolina Professional Association; MUHAMMAD AKRAM PARACHA, M.D.; and VALLEY CARDIOLOGY, P.A., a North Carolina Professional Association,

Defendants.

Case No.: 5:16-CV-955-BR

COMPLAINT and JURY DEMAND

ORIGINAL COMPLAINT FILED IN CAMERA AND UNDER SEAL, PURSUANT TO 31 U.S.C. §3730(b)(2)

*****DO NOT PLACE IN PRESS BOX*****

*****DO NOT ENTER ON PACER*****

NOW COMES PLAINTIFF-RELATOR, John Doe, by and through his attorneys, Charles H. Rabon, Jr., Daniel J. Finegan, and Gregory D. Whitaker, of the Rabon Law Firm, PLLC, and brings this action under 31 U.S.C. §§3729–3732 (the "federal False Claims Act"), and N.C. Gen. Stat. §§1-605 to 1-618 (the "North Carolina False Claims Act"), to recover all damages, penalties and other remedies established by the federal False Claims Act and North Carolina False Claims Act, on behalf of the United States, the State of North Carolina, and himself, and shows the Court as follows:

I. OVERVIEW

1. This is an action alleging that the Defendants submitted false and/or fraudulent claims to Medicare, Medicaid, and TRICARE in connection with non-covered and medically

unnecessary services in regard to certain medical procedures and services rendered by the Defendants and billed to Medicare, Medicaid, and TRICARE.

II. JURISDICTION

2. This action arises under the federal False Claims Act, 31 U.S.C. §3729, *et seq.*

3. Jurisdiction over this action is conferred upon this Court by 31 U.S.C. §3732(a) and 28 U.S.C. §1331, in that this action arises under the laws of the United States. Pendent jurisdiction over the related state law claims (under the North Carolina False Claims Act) is conferred by 28 U.S.C. §1367.

4. Venue is proper in this district pursuant to 31 U.S.C. §3732(a), which provides that "any action under §3730 may be brought in any judicial district in which the Defendant or, in the case of multiple Defendants, any one Defendant can be found, resides, transacts business, or in which any act proscribed by §3729 occurred." At all times material hereto, the Defendants resided and regularly conducted business within the State of North Carolina, within this judicial district. Moreover, acts proscribed by §3729, and giving rise to this action, occurred within this judicial district.

5. There are no bars to recovery under 31 U.S.C. §3730(e) or N.C. Gen. Stat. §1-611. Specifically, substantially the same allegations as those alleged in this suit have not been publicly disclosed in a federal criminal, civil, or administrative hearing in which the Government or its agents were a party, *or* in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation, *or* from the news media. In the alternative, Relator is an original source as defined in 31 U.S.C. §3730(e). Relator has knowledge that is independent of and materially adds to any publicly disclosed allegations or transactions. Further, this action is not based upon the public disclosure of allegations or

transactions in a criminal, civil, or administrative hearing at the State or federal level, *or* in a congressional, legislative, administrative, General Accounting Office, or State Auditor's report, hearing, audit, or investigation, *or* from the news media. In the alternative, Relator is an original source as defined in N.C. Gen. Stat. §1-611(d). Relator has direct and independent knowledge of the information on which the allegations are based.

III. PARTIES

6. Relator is a resident of Pennsylvania.

7. Hari Parshad Saini, M.D. ("Dr. Saini") is a physician licensed by the North Carolina Medical Board to practice medicine within the State of North Carolina. Dr. Saini was first licensed by the North Carolina Medical Board on June 19, 2003, and his NCMB License number is 200300698.

8. Carolina Heart and Leg Center, P.A., ("CHLC") is a Professional Corporation organized and existing under the laws of the State of North Carolina. CHLC was created as a Professional Association on August 1, 2013. CHLC was formed by Dr. Saini for the purpose of conducting a medical practice. CHLC's principal office location is at 3637 Cape Center Dr., Fayetteville, NC 28304. CHLC's principal office is owned by 3637 Cape Center Drive EAT, LLC, a North Carolina limited liability company owned all or in substantial part by Dr. Saini.

9. Dr. Muhammad Akram Paracha ("Dr. Paracha") is a physician licensed by the North Carolina Medical Board to practice medicine within the State of North Carolina. Dr. Paracha was first licensed by the North Carolina Medical Board on September 20, 2001, and his NCMB License number is 200101260.

10. Valley Cardiology P.A. ("Valley Cardiology") is a Professional Corporation organized and existing under the laws of the State of North Carolina. Valley Cardiology was created as a

Professional Association on July 3, 2013. Valley Cardiology was formed by Dr. Paracha for the purpose of conducting a medical practice. Valley Cardiology's principal office location is at 3656 Cape Center Dr., Fayetteville NC 28304. Valley Cardiology's principal office is owned by Zubeda, LLC, a North Carolina limited liability company owned all or in substantial part by Dr. Paracha.

IV. BACKGROUND

A. Overview of Defendants and Brief Nature of Case

11. CHLC is a cardiology clinic located in Fayetteville, NC. CHLC advertises that it offers a full range of cardiology and vascular services to include: echocardiogram, arterial and venous duplex ultrasound, carotid ultrasounds, abdominal aortic ultrasounds, ABI, holter and event monitoring, nuclear stress testing, and full lab services. According to the CHLC website, the clinic also offers the following: a state of the art peripheral angiogram lab, specializing in stentless treatment of leg blockages and a venous lab specializing in minimally invasive treatment of varicose and spider veins. See http://www.carolinaheartandleg.com/.

12. Dr. Saini is a board certified interventional cardiologist who specializes in venous, arterial, and coronary interventions.

13. Dr. Saini opened the CHLC in or around December, 2014. Prior to creating CHLC, Dr. Saini was in a partnership with Dr. Paracha in a medical practice named Carolina Cardiology, P.A. ("Carolina Cardiology"). This partnership broke up in the summer of 2013, as described more fully below.

14. Dr. Paracha is a board certified specialist in Cardiovascular Disease and Interventional Cardiology, with primary practice areas of Cardiovascular Disease and Internal Medicine, along with Interventional and Nuclear Cardiology.

15. Relator was employed as a cardiologist with CHLC from July 2015 until July 2016.

16. As described more fully herein, Relator witnessed widespread unlawful activity regarding the intentional incorrect diagnosis of medical conditions, performance of unnecessary medical procedures and surgeries, and knowingly unlawful billing activity with government payors during the time that he was in practice as an employee of CHLC and Dr. Saini.

17. Through multiple conversations with Dr. Saini and other CHLC employees, Relator discovered that these unlawful practices were learned and developed by Dr. Saini during the period when he [i.e., Dr. Saini] practiced with Dr. Paracha at Carolina Cardiology.

18. In 2012, Drs. Saini and Paracha received Medicare payments in the amounts of $898,116 and $2,371,377, respectively.[1]

19. In 2013, Drs. Saini and Paracha received Medicare payments in the amounts of $752,833 and $1,395,506, respectively.

20. In 2013, Drs. Saini and Paracha experienced a significant falling out over compensation issues in their practice. In breaking up their medical practice, Drs. Saini and Paracha applied to Cumberland County Superior Court to appoint a receiver over some or all of their jointly controlled entities and assets.

21. In 2014, Dr. Saini and Dr. Paracha each started his own lucrative cardiology practice so that they did not have to share revenues as medical partners. In 2014 – now each in his own practice – Drs. Saini and Paracha received Medicare payments in the amounts of $2,912,389 and $2,787,905, respectively.

[1] These amounts represent payments made by Medicare for a limited range of procedures (covered by just a handful of CPT codes) that are the subject of this action, and which are believed and therefore it is so alleged, were to a large degree medically unnecessary. These amounts represent only Medicare as payor, and do not reflect any payments by TRICARE, Medicaid, or any other payor.

22. After the medical practice of Drs. Saini and Paracha were split, both doctors continued and expanded their system of unlawful practices as more fully described herein.

B. Part B Medicare Coverage

23. Medicare is a federally funded health care program for individuals over the age of 65 and individuals that are disabled. Medicare is comprised of Parts A, B, C, and D. Part B is medical insurance that authorizes payment of federal funds for health services, including physician, laboratory, outpatient, diagnostic, and radiology services. 42 U.S.C. § 1395k; 42 C.F.R. § 410.10.

24. Medicare will not cover items and services that are not indicated, not reasonable, or not medically necessary. See 42 U.S.C. § 1395y(a)(1)(A) (2012); 42 C.F.R. § 411.15(k)(1) (2012).

25. Among other things, Medicare providers must assure that (a) their services are rendered "economically and only when, and to the extent, medically necessary." 42. U.S.C. § 1320c-5(a)(1); and (b) that such services are "of a quality which meets professionally recognized standards of health care." 42. U.S.C. § 1320c-5(a)(2).

26. "Services 'related to' non-covered services . . . including services related to follow-up care and complications of non-covered services which require treatment during a hospital stay in which the non-covered service was performed, are [also] not covered services under Medicare." Centers for Medicare & Medicaid Services, Medicare Benefit Policy Manual, Ch. 16, § 180, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html.

27. Providers of medical services under Part B must present claims to Medicare on the CMS Form 1500 (Health Insurance Claim Form). On Form 1500, the provider certifies, among other things, that their services were medically necessary.

28. Providers of medical services under Part B also make certifications to the United States Government in provider enrollment agreements on CMS Form 855b and/or CMS Form 855i.

29. Form 855b covers clinics, group practices, and certain suppliers. Form 855i covers physicians and certain non-physician medical practitioners.

30. In reliance on these certifications, CMS makes Medicare payments to such Part B providers for medical services rendered.

31. Dr. Saini is a registered Medicare provider in Fayetteville, North Carolina.

32. CHLC is a registered Medicare clinic and/or group practice.

33. Dr. Paracha is a registered Medicare provider in Fayetteville, North Carolina.

34. Valley Cardiology is a registered Medicare clinic and/or group practice.

C. Peripheral Arterial Disease (PAD)

35. PAD is the narrowing or blockage of the vessels that carry blood from the heart to the arms and legs. It is primarily caused by the buildup of fatty plaque in the arteries, which is called atherosclerosis. PAD can occur in any blood vessel, but it is more common in the legs than the arms. See http://www.cdc.gov/dhdsp/data_statistics/fact_sheets/docs/fs_pad.pdf.

36. PAD symptoms and signs include pain in the legs when walking, muscle atrophy, hair loss, smooth shiny skin, skin that is cool to the touch especially if accompanied by pain while walking (which is relieved by stopping walking), decreased or absent pulses in the feet, non-healing ulcers or sores on the legs or feet, and cold or numb toes.

37. People who have PAD can have symptoms even without visible physical signs. However, as many as 40% of patients with PAD do not experience any leg pain. Similarly, not all persons who have leg pain in fact have arterial disease such as PAD and they do not need invasive treatments which, for such persons, would not be medically indicated and would therefore be medically unnecessary.

38. In symptomatic patients, Peripheral Arterial Disease is often diagnosed through medical tests such as ankle-brachial index (ABI), a non-invasive test that measures the blood pressure in the ankles and compares it with the blood pressure in the arms at rest and after exercise, ultrasound, magnetic resonance angiography (MRA), and computed tomographic (CT) angiography.

39. Non-invasive treatment for PAD can consist of use of medications (statins, aspirin, etc.) and dietary and lifestyle modifications.

40. If non-invasive tests corroborate the severity of PAD in a patient, and if clotting or pain has become disabling, a physician may perform invasive tests to determine if revascularization (i.e., invasive surgical methods to restore blood flow) is necessary.

41. An Angiogram is one such invasive testing procedure. In an angiogram, a catheter is inserted into a blood vessel in an affected limb and guided to the area of concern with the use of a fluoroscope. The catheter is then used to inject a dye into the vessel and the results observed through the fluoroscope.

42. There are three common forms of invasive treatment for PAD – balloon angioplasty, stent placement, and atherectomy. All of these procedures expose patients to risk of harm and can lead to other medical problems.

43. Balloon angioplasty involves inflating a small balloon via catheter inside the affected portion of the blood vessel after treating the patient with anti-coagulant drugs. Stents are small metallic mesh tubes that are inserted into an affected vessel, and are typically used in conjunction with balloon angioplasty. Atherectomy is accomplished by physically removing the plaque built-up inside the vessel. This is typically done with a small blade or laser placed into the vessel via catheter.

44. Each of these procedures carries inherent risks. Among other known risks, blood vessels can tear during catheterization, stents can unexpectedly block blood flow in other nearby blood vessels, and plaque removal can enter the blood stream and cause stroke or heart attack.

D. Chronic Venous Insufficiency (CVI)

45. CVI is a common form of vascular disease. Venous insufficiency, which can cause varicose veins, has been described as follows: "Venous insufficiency is a very common condition resulting from decreased blood flow from the leg veins up to the heart, with pooling of blood in the veins. Normally, one-way valves in veins keep blood flowing toward the heart—against the force of gravity. When the valves do not perform their function, blood can flow backwards or reflux. This reflux results in what is known as venous insufficiency, a very common condition that results in the pooling of blood in the veins." CVI is often associated with varicose veins, which are twisted, enlarged veins close to the surface of the skin. They can occur almost anywhere, but most commonly occur in the legs.

46. People who have venous insufficiency can have symptoms even without visible varicose veins. Veins afflicted with venous reflux disease can be deep within a person's leg, such that there is no physical or visible indication of the condition. Similarly, not all persons who have leg pain in fact have vein disease such as venous reflux and they do not need invasive

treatments which, for such persons, would not be medically indicated and would therefore be medically unnecessary.

47. In modern medicine, vein disease such as venous reflux is typically diagnosed by duplex ultrasound examination of one's venous system. The ultrasound is performed by an ultrasound technician who operates the ultrasound diagnostic equipment and then provides the test results to be interpreted by a qualified physician or radiologist.

48. Most patients with venous insufficiency are treated with conservative measures like stockings. Some patients who have persistent symptoms in spite of wearing stockings for several months (i.e. failed conservative measures) are treated with invasive treatment. In the past, invasive treatment used to be a surgery called vein stripping performed in an operation theater, but current state of the art treatment for such patients who fail to improve with conservative measures is endovenous laser ablation therapy (EVLA) done in outpatient office setting.

49. EVLA involves the insertion of catheter and laser filament into the vein. The position of the laser is confirmed with ultrasound, and the laser is used to seal the target blood vessel. The sealed vein does not reflux any more and patients' symptoms improve. The role of EVLA is only to improve symptoms and therefore if a patient with venous reflux does not have symptoms or has minimal symptoms, there is no indication for EVLA. There are specific criteria for severity of symptoms required by the government and private payors before they will pay for such invasive treatments.

50. Approximately 5-30% of patients screened for venous disease have reflux on duplex ultrasound. Of these, most patients either do not have significant symptoms or have improvement in symptoms with conservative measures. Patients with advanced symptoms

which do not improve with conservative measures may require invasive treatment for reflux like EVLA or sclerotherapy.

51. For medical practices that perform EVLA, payor reimbursement rates (both private insurance and government payors such as Medicare, Medicaid, and Tricare) are high. EVLA can be a lucrative source of income for such practices.[2]

E. Medicare Reimbursement for PAD, EVLA, and Related Diagnostic Tests and Procedures

52. As stated herein, Medicare will not cover items and services that are not indicated, not reasonable, or not medically necessary. See 42 U.S.C. § 1395y(a)(1)(A) (2012); 42 C.F.R. § 411.15(k)(1) (2012). This standard applies to treatment of PAD and the use of angioplasty, stent implantation, and atherectomy in peripheral arteries.

53. When a peripheral artery is more than 50% percent blocked, a patient may be determined to have "clinically significant" PAD. See Jeffrey L. Anderson, et al., "Management of Patients with Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendation)," Journal of the American College of Cardiology, Vol. 61, No. 14 (Apr. 2013).

54. As a general principle, "[e]ndovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity PAD." Id. Thus, prior to performing an interventional procedure in the peripheral arteries, Medicare providers must assess the medical necessity of the intervention through a detailed evaluation, and thoroughly document the clinical indications necessitating the intervention.

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[2] "In addition to favorable clinical results and increased patient demand, [EVLA] procedures performed on an outpatient basis can be expected to significantly increase revenues. With proper strategy and organization, an outpatient vein practice can round out the existing vascular practice and be a profitable adjunct to an already established vascular surgery practice." C.K. Shortell & J.N. Markovic, Incorporating Outpatient Venous Procedures Into A Vascular Surgery Practice, Journal of Vascular Surgery, Volume 50, Issue 1, Pages 225–230, July 2009 (quote taken from article abstract).

55. In general, only after a Medicare provider has exhausted non-invasive tests and treatments—and after symptoms prove to be recurrent—should invasive procedures be performed on patients with severe PAD. "Because of the variability of individual . . . symptoms and variable impact of these symptoms on quality of life, patients should be selected for revascularization on the basis of the severity of their symptoms; a significant disability as assessed by the patient; failure of medical therapies; lack of significant comorbid conditions; vascular anatomy suitable for the planned revascularization; and a favorable risk/benefit ratio." Alan T. Hirsch, et al., "ACC/AHA 2005 Practice Guidelines for the Management of Patients with Peripheral Arterial Disease," Circulation (2006).

56. Treatment of PAD through atherectomy, angioplasty, and stent implantation are covered under Medicare and there are several CPT Codes relevant to them. These include, but are not limited to:

    a. CPT Code 37221 (Insertion of stents in artery in one side of groin, endovascular);
    b. CPT Code 37224 (Balloon dilation of arteries in one leg, endovascular);
    c. CPT Code 37225 (Removal of plaque in arteries one leg, endovascular);
    d. CPT Code 37226 (Insertion of stets into arteries in one leg, endovascular);
    e. CPT Code 37227 (Removal of plaque and insertion of stents into arteries in one leg, endovascular);
    f. CPT Code 37228 (Balloon dilation of artery of one leg, endovascular);
    g. CPT Code 37229 (Removal of plaque in artery in one leg, endovascular);
    h. CPT Code 37232 (Balloon dilation of artery in one leg, endovascular); and
    i. CPT Code 37233 (Removal of plaque in artery in one leg, endovascular);

57. EVLA is covered by Medicare, and there are several CPT Codes relevant to EVLA.

a. CPT Code 36478, (Endovenous laser first vein), is the CPT code for the initial ELVA performed;

b. CPT Code 93971, (Unilateral or limited extremity study), is the CPT code for the follow-up ultrasound post-surgery; and

c. CPT Code 36479, (Endovenous laser vein add-on), is the CPT Code for any additional laser procedures that need to be performed after the initial procedure.

58. CPT Code 93970, Bilaterally Extremity Study, is the CPT code representing the initial diagnostic ultrasound to determine whether EVLA should be performed. CPT Code 93970, like all radiology services, has both a Professional Component (PC) and Technical Component (TC).

59. The PC is the portion of the services provided by the physician including interpreting the diagnostic test and a written report. See Centers for Medicare & Medicaid Services, Medicare Claims Processing Manual, Ch. 13, § 20.1, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html.

60. The TC is for all non-physician work. See Medicare Claims Processing Manual, supra, at § 20.2.

61. Although the physician is not required to perform the actual procedure (e.g., the ultrasound) so long as there is adequate supervision of qualified personnel, the physician is required to interpret the results (i.e., make the final diagnosis).

62. As Medicare providers, Defendants were obligated to understand and certify their compliance with all applicable Medicare laws, regulations, and program instructions as a condition of participation in Part B and as a condition of payment of Medicare reimbursements.

63. Medicare providers like Defendants are reimbursed for covered services based on their submission of an electronic or hard-copy claim form called the CMS Form 1500 Health Insurance Claim Form.

64. When submitting claims to Medicare, providers certify on CMS Form 1500, *inter alia*, that: (a) the services rendered are "medically indicated and necessary for the health of the patient"; (b) the information on the claim form is "true, accurate and complete"; and (c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal and State laws." After a February 2012 revision to CMS Form 1500, providers further expressly certify that their claims comply "with all applicable Medicare . . . laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law)."

65. CMS Form 1500 also requires providers to acknowledge that: "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."

66. Because it is not feasible for Medicare personnel to review every patient's medical records for the millions of claims for payments they receive from providers, the program relies on providers to comply with Medicare requirements and trusts providers to submit truthful and accurate certifications and claims.

67. Generally, once a provider submits CMS Form 1500 to the Medicare, the claim is paid directly to the provider without any review of supporting documentation, including medical records.

F. The Anti-Kickback Statute

68. The Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), arose out of Congress' concern that remuneration given to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these harms, Congress enacted a prohibition against payment of kickbacks in any form. See Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

69. The AKS prohibits any person or entity from knowingly and willfully soliciting or receiving remuneration to induce or reward any person for referring, recommending, or arranging for federally-funded medical services, including services provided under the Medicare program. See 42 U.S.C. § 1320a-7b(b).

70. In 2010, Congress amended the AKS to clarify that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148 § 6402(f), 124 Stat. 119, 759, codified at 42 U.S.C. § 1320a-7b(g).

G. History of CHLC, Valley Cardiology, and Drs. Saini's and Paracha's Operations

71. Drs. Saini and Paracha joined Carolina Cardiology on or around September 17, 2004. Together, they practiced at Carolina Cardiology until around July 2013.

72. In 2008, in an attempt to curb rising Medicare costs in hospitals, the Center for Medicare and Medicaid Services ("CMS") payment rules were changed to allow for outpatient procedures such as PAD, which was designed to treat medical conditions affecting blocked blood vessels in limbs.

73. After this change in Medicare rules, treatment for these procedures in outpatient clinic settings increased significantly. Beginning no later than 2012, Dr. Paracha realized the potential for significant revenue generation by seeing more Medicare covered patients and performing as many tests, invasive treatments, and follow-up appointments and courses of treatment as possible. Because these patients were all covered by Medicare, Dr. Paracha focused on the highest paying procedures and collected a much higher volume of payments than an ordinary cardiologist would in similar circumstances.

74. Upon information and belief, Dr. Saini and Dr. Paracha split in 2013 because Dr. Saini became aware of the significant Medicare payments Dr. Paracha was receiving as a result of his unlawful practices, which resulted in Dr. Paracha earning substantially more money than Dr. Saini.

75. However, Dr. Saini was not alarmed by the illegality of Dr. Paracha's practice, but was rather envious of the significant payments he was receiving. Dr. Saini left his practice with Dr. Paracha and created a similar system with CHLC.

76. After learning the methods of Dr. Paracha's illegal scheme, in 2014 Dr. Saini's Medicare payments increased by **387%** from his prior year's amount ($752,833 to $2,912,389).

77. In December 2014, Relator travelled to Fayetteville to interview with Dr. Paracha. Relator was previously aware that Drs. Paracha and Saini practiced together at Carolina Cardiology.

When he learned of the split and formation of separate practices in his interview with Dr. Paracha, he called Dr. Saini to inquire about the matter.

78. In a telephone call, Dr. Saini told Relator that Dr. Paracha was "a crook" and that, for years Dr. Paracha had been (a) falsely diagnosing PAD conditions in patients in order to conduct treatments that would be billed to Medicare; (b) breaking up these procedures into multiple courses of treatment in order to maximize the total Medicare payments to his clinic; and (c) billing Medicare for these unnecessary procedures.

79. Dr. Saini presented this history of unlawful practices as the basis which caused the split between himself and Dr. Paracha. Dr. Saini also referred to the fact that Dr. Paracha was generating millions of dollars in fees by treating Medicare patients that Dr. Saini believed he needed to expand his Medicare practice. Based on this conversation and the facts Dr. Saini conveyed to Relator, Relator became very uncomfortable with the idea of working with Dr. Paracha.

80. In the same conversation, Dr. Saini offered Relator a position working with CHLC. Dr. Saini offered an initial twenty-four month contract term to work as a cardiologist with CHLC.

81. Relator accepted the offer of employment and began his work with CHLC on July 27, 2015.

82. The majority of Relator's work was to oversee follow-up visits with Dr. Saini's patients after they had already undergone a course of invasive exams and treatment like angiograms, angioplasty, and atherectomies.

83. Over the course of several months, Relator realized that the very practices which Dr. Saini attributed to Dr. Paracha were being carried out at CHLC.

84. As Relator treated increasing numbers of Dr. Saini's patients, and examined their medical records and histories, he saw a pattern emerge: Relator saw that as patients came into CHLC

for evaluation, they were put through a process to ensure that the maximum number of procedures would be carried out, and that these procedures would be broken out into multiple courses of treatment in order to generate the highest amount of Medicare payments possible. Frequently, patients would be put through multiple rounds of invasive exams and treatments without a proper diagnosis of symptoms or without a proper assessment of risk factors.

85. During his time at CHLC, Relator was given a clinic-wide memo that the imaging technicians were not busy enough, and that each physician should order more imaging tests. This was dictated by Dr. Saini and was intended to be followed regardless of whether Relator believed the test was indicated, reasonable, or medically necessary.

86. Relator was instructed to order two to three tests for each patient, on each visit, regardless of whether the tests were indicated, reasonable or medically necessary. Relator was also instructed as to the verbiage to be used in medical records and standards required to ensure approval by Medicare for payment of the tests.

87. The stated CHLC goal for each patient was to ultimately "max out" the possible Medicare billings at around $12,000 to $15,000 per patient.

88. For each patient, the standard course of procedures was to first conduct the ABI exam. The ABI exams were almost always found to have "abnormal results," which in turn justified the need for ultrasound and/or arterial duplex examinations. Any time the images/results from these exams indicated any vascular stenosis in the patients' arteries, the patient was almost always determined by Dr. Saini to have "abnormal results" or be 60-70% blocked, which in turn justified invasive angiogram procedures, angioplasty, atherectomy, and stent implantation. This pattern continued through follow up appointments and procedures scheduled a few months after the prior round of tests and treatments.

89. Dr. Saini failed to order and exhaust non-invasive tests and conservative treatments before performing invasive tests and treatments. Dr. Saini also failed to rule out alternative, non-vascular causes of patients' symptoms before performing invasive treatments.

90. CHLC electronic medical records ("EMR") were pre-populated with affirmative diagnosis boxes checked indicating "abnormal results" and/or the presence of 60-70% blocked vessels before any medical personnel reviewed or completed the forms.

91. Dr. Saini also obtained venous ultrasounds to look for venous reflux in almost all the patients visiting CHLC. In Relator's experience, almost 70% of these patients did not have symptoms or physical signs of venous reflux and did not warrant venous ultrasound study. The technicians obtaining the ultrasound images were instructed by Dr. Saini to measure the 'reflux time' in such a way that it comes to be at least greater than 0.5 sec. Any reflux greater than 0.5 seconds meets qualifying criteria (both for governmental and private payors) for payment for treatment of venous reflux.

92. In Relator's experience, almost 70% of patients that visited CHLC underwent venous reflux study and out of those, Dr. Saini read almost 90% as abnormal for reflux. A normal practice would struggle to find more than 5-10% of patients with true venous reflux.

93. Consequently, a large number of patients at CHLC were carrying a diagnosis of venous reflux and were scheduled for EVLA with employee doctors in the practice. Based on this "abnormal" interpretation of venous ultrasound, most of these patients would undergo multiple venous ablation procedures in Dr. Saini's medical practice. The office was performing about 15-20 venous ablation procedures a week. This large volume was primarily driven by Dr. Saini's systematic practice of performing venous ultrasound on almost all the patients walking into his practice and then falsely interpreting the venous

ultrasound studies to somehow document greater than 0.5 seconds of venous reflux. Based on Relator's review of venous ultrasound studies, only approximately 1 out of 10 patients scheduled for invasive venous reflux treatment via EVLA and/or sclerotherapy actually needed such invasive treatments. Relator also learned by interviewing these patients that it was a common practice to falsify symptoms in medical records to meet insurance criteria and justify such treatments. Relator confirmed his suspicions by reviewing ultrasound and angiogram images of several patients treated at CHLC and saved records of six such patients (Patients A through F) as evidence. All these patients seemed to be unreasonable candidates for the course of treatment they had endured based on Dr. Saini's false diagnoses and at his urging.

94. Relator accessed these patient's ultrasound images and reviewed them to determine whether the course of treatment taken was indicated, reasonable, and/or medically necessary. In each of the six cases where he was able to review the ultrasound images, he found no objective medical support for Dr. Saini's diagnosis or course of treatment taken.

i. Patient A

95. Patient A was a 67 year old male. At the follow up appointment with Relator in late December 2015, Patient A was experiencing no symptoms of PAD or other cardiovascular complaints.

96. In June 2015, Patient A had undergone an Echocardiogram and Arterial Duplex Ultrasound at CHLC.

97. Based on the results of these tests, in September 2015, Patient A had undergone an atherectomy and percutaneous transluminal angioplasty ("PTA") procedure on his left posterior tibial artery ("PT"), tibioperoneal trunk ("TP trunk") and superficial femoral artery

("SFA"). At that time, Patient A was also advised to undergo follow up procedures at a later date for (a) angioplasty and/or atherectomy of his left peroneal and (b) PTA for his right popliteal artery and SFA.

98. In December 2015, Patient A had an angiogram procedure, followed by atherectomy and PTA of his right peroneal artery, popliteal artery, and SFA. He was recommended to undergo a follow up ultrasound procedure in six months. The recommended procedure for angioplasty and/or atherectomy of his left peroneal was still outstanding.

99. Prior to the battery of invasive procedures in September and December 2015, there was no medical record evidence of non-invasive attempts at treatment. When Relator accessed Patient A's ultrasound images, he saw no evidence supporting the course of invasive treatment given by Dr. Saini and CHLC.

100. When Relator saw Patient A in the office during a follow up visit in July 2016 and asked the patient about his leg symptoms, Patient A stated that he had never really experienced leg pain. When Relator asked him what lead to all his leg procedures, Patient A stated the procedures were undertaken "because [Dr. Saini] did some testing on his legs and found blockages in both legs and told me that I needed to get those fixed."

101. Based on his medical records, Patient A had undergone four echocardiograms (in 2007, 2008, 2011, and 2015) which were all essentially normal. This indicates gross overutilization of diagnostic testing procedures.

ii. Patient B

102. Patient B was an 81 year old female, initially referred to CHLC for evaluation of PAD because of leg pains and mildly abnormal ABI done at an outside office.

103. Relator saw Patient B in the office and ordered an arterial ultrasound to further assess for PAD. Dr. Saini interpreted the ultrasound as abnormal and had his nurse call the patient and inform her about blockages in her legs. The Patient was thereupon scheduled for lower extremity angiogram with Dr. Saini. Relator was not involved in the decision to perform an angiogram.

104. Patient B came in to the office for lower extremity angiogram where she met Dr. Saini for the first time. During the angiogram the patient underwent angioplasty and atherectomy of the left SFA and popliteal artery and angioplasty and thrombectomy of left peroneal artery. During the procedure, the patient had a major life threatening bleeding complication requiring emergency hospitalization, blood transfusions, and vascular surgery.

105. When Relator accessed the angiogram images, he determined that there were no significant blockages on angiogram that required atherectomy and angioplasty. Patient B's case is an example of how Dr. Saini's and CHLC's overuse of invasive and unnecessary procedures can be associated with life threatening complications.

iii. Patient C

106. Patient C was a 63 year old female. At the follow up appointment with Relator in late early March, 2016, Patient C was experiencing no symptoms of PAD or other cardiovascular complaints.

107. In January 2016, Patient C had undergone an Arterial Duplex Ultrasound at CHLC. Dr. Saini diagnosed severe disease of the right SFA, along with moderate to severe disease in the left SFA and common femoral artery ("CFA").

108. Patient C was never prescribed essential drugs for non-invasive medical management of PAD including aspirin and statin drugs prior to the invasive treatments.

109. Based on the results of these tests, in February 2016, Patient C had undergone an angiogram in 2016 in which procedure Dr. Saini also performed atherectomy and PTA procedure on her right SFA. Patient C was also advised to undergo staged atherectomy and PTA of her left SFA and anterior tibial artery ("AT") at a later date.

110. Prior to the battery of invasive procedures in February 2016, there was no medical record evidence of non-invasive attempts at treatment. When Relator accessed Patient C's ultrasound images, he saw no evidence supporting the course of invasive treatment given by Dr. Saini and CHLC.

iv. Patient D

111. Patient D was a 63 year old female. At the follow up appointment with Relator in late March 2016, Patient D was experiencing some leg pain symptoms with exertion, but no leg swelling or other cardiovascular complaints that signified support for diagnosis of PAD.

112. From February 2015 through February 2016, Patient D underwent repeated invasive examinations and procedures including angiogram, atherectomy and PTA of her right SFA and popliteal artery, and atherectomy and PTA of her left AT, popliteal artery, and SFA.

113. Prior to the battery of invasive procedures, there was no medical record evidence of non-invasive attempts at treatment. When Relator accessed Patient D's ultrasound images, he saw no evidence supporting the course of invasive treatment given by Dr. Saini and CHLC.

114. Patient D, like several other patients seen at CHLC, underwent a wide range of cardiac tests that were not required. Patient D had a cardiac catheterization in 2013, nuclear stress test in 2015, and an echocardiogram in 2015 which were all normal. Patient D also had a bleeding complication from lower extremity angiogram and intervention performed by Dr. Saini in October 2015. This resulted in pain, blood loss, and temporary disability for this

patient. A repeat arterial ultrasound testing in November 2015 confirmed a 9.7 x 7.3 cm collection of blood (hematoma) in Patient D's left leg.

115. Patient D not only underwent unnecessary arterial intervention, but also an unnecessary venous ablation procedure. Relator has personally reviewed several other patients' venous ultrasounds and confirmed that they were falsely interpreted as abnormal by Dr. Saini to justify a large volume of unnecessary venous ablation procedures at CHLC. Dr. Saini typically manipulated the measurements in these ultrasounds to report abnormal reflux which then triggers a venous ablation procedure. The report of '1.1 sec' reflux was a typical misinterpreted venous ultrasound.

116. Patient D also underwent venous ultrasound of legs which were interpreted by Dr. Saini as right GSV reflux for 1.1 sec in June 2015. Patient D had a repeat venous duplex ultrasound in November 2015 which did not show any venous reflux. Despite the findings from the November 2015 venous duplex, the patient then underwent right GSV ablation on February 5, 2016.

v. Patient E

117. Patient E was a 79 year old female. At the follow up appointment with Relator in early April 2016, Patient E was experiencing leg pain and swelling.

118. From January 2015 through September 2015, Patient E underwent repeated invasive examinations and procedures including angiogram, atherectomy and PTA of her right SFA, and atherectomy and PTA of her left popliteal artery and SFA.

119. Prior to the battery of invasive procedures, there was no medical record evidence of non-invasive attempts at treatment. When Relator accessed Patient E's ultrasound images, he saw no evidence supporting the course of invasive treatment given by Dr. Saini and CHLC.

vi. Patient F

120. Patient F was a 70 year old female. At the follow up appointment with Relator in late June 2016, Patient F was experiencing some pain and stiffness in her right knee area.

121. From August 2015 through March 2016, Patient F underwent repeated invasive examinations and procedures including angiogram, atherectomy and PTA of her right SFA, TP trunk, peroneal and popliteal artery, and angioplasty of her left SFA and AT.

122. Prior to the battery of invasive procedures, there was no medical record evidence of non-invasive attempts at treatment. When Relator accessed Patient F's ultrasound images, he saw no evidence supporting the course of invasive treatment given by Dr. Saini and CHLC. When Relator interviewed Patient F about her leg symptoms prior to the invasive leg procedures, Relator determined that she had never experienced symptoms of PAD. The pain and stiffness referred to are more commonly caused by orthopedic issues, and Relator referred Patient F for orthopedic evaluation.

H. Additional Patients and Common Practices between Paracha and Saini

123. In his time at CHLC, Relator saw dozens of patients on follow up visits that had undergone atherectomy or other invasive procedures by Dr. Saini and CHLC. Relator determined that, at most, perhaps only approximately 30% of these patients were suitable candidates for atherectomy or other invasive procedures.

124. Dr. Saini and the staff at CHLC failed to document the clinical need for the invasive PAD interventions that they performed so frequently. Instead, they developed and relied upon a variety of record-keeping shortcuts including the use of pre-populated EMR forms wherein

the desired test results were pre-selected, and dissemination of known diagnosis codes and acceptable test results to justify further treatments.

125. Dr. Saini's gross overutilization of Medicare services for the vulnerable population significantly deviated from what other cardiovascular specialists like Relator consider reasonable and appropriate.

126. Dr. Saini learned his illicit practices from his time with Dr. Paracha. Dr. Paracha had implemented the same system of unnecessary diagnoses and treatments, and like Dr. Saini, Dr. Paracha's gross overutilization of Medicare services for the vulnerable population significantly deviated from what the other cardiovascular specialists consider reasonable and appropriate.

127. During his time at CHLC, Relator treated and examined four to five patients who had previously been patients of Dr. Paracha. For each such patient Relator noticed the same pattern of over-diagnosis, unnecessary intervention, and improper use of invasive procedures as has been described herein as being Dr. Saini's practices at CHLC. In each case, examining the medical records and patient history of symptoms and courses of treatment, Relator saw no evidence to support the courses of treatment undertaken by Dr. Paracha.

I. Defendants' Knowing False Certifications

128. As alleged herein, throughout the relevant period, Defendants actually knew that that their certifications and claims for reimbursement submitted to Medicare, Medicaid and TRICARE were false, or else deliberately ignored, and/or were recklessly indifferent to, the truth or falsity of those certifications and claims.

129. As alleged herein, Defendants knew that they were performing medically unnecessary procedures and failing adequately to document medical necessity.

130. By way of specific example, Relator's experience was initially focused on conducting venous ablation procedures as ordered by Dr. Saini. On more than one occasion, Relator confronted Dr. Saini and tried to tell him that his practices were wrong and illegal. Dr. Saini responded that Relator's job was to "just do the procedures, I am the one who is reading the ultrasound and if I have decided that the patient needs [the treatment], then your job is to just do the procedure. You should not question my clinical judgment."

131. Relator used to cancel the procedures scheduled for ablation whenever he could determine that it was a "made up" case. However, the volume of patients was overwhelming and it was practically difficult for Relator to review each ultrasound and clinical history and cancel all the unnecessary procedures. Additionally, many patients had been told by Dr. Saini that they have venous reflux and were anxiously waiting for venous ablation procedure for months.

132. The Defendants made, used, and/or caused to be made or used, false records and/or statements material to false or fraudulent claims in order to be reimbursed by government programs such as Medicare, Medicaid, and TRICARE. Those false records and/or statements include, but are not limited to, certifications of compliance (both explicit and implied) with applicable laws, federal regulations, and CMS Manuals, guidelines and regulations, as set forth herein above.

133. As a direct result of the Defendants submission of false and/or fraudulent claims for payment, the Defendants have received significant sums of money to which they are not legitimately entitled. The United States and the State of North Carolina, therefore, have suffered substantial damages in amounts to be proven by the evidence.

V. CAUSES OF ACTION

FIRST CLAIM FOR RELIEF
(FALSE CLAIMS – 31 U.S.C. §3729(a)(1)(A))

134. The allegations of all paragraphs in this Complaint are incorporated by reference.

135. In performing the acts described above, the Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly presented, and/or caused to be presented, to an officer or employee of the United States Government, false or fraudulent claims for payment or approval under Medicare, Medicaid, and TRICARE, in violation of 31 U.S.C. §3729(a)(1)(A).

136. As a direct result of the Defendants' fraudulent conduct, the United States government has been damaged in amounts to be determined at trial.

137. Additionally, the United States is entitled to penalties of up to $11,000 for each and every violation of 31 U.S.C. §3729(a)(1)(A) by the Defendants. However, civil penalties under 31 U.S.C. §3729(a) shall be up to $21,563 per violation for penalties assessed after August 1, 2016, where the FCA violations occurred after November 2, 2015.

SECOND CLAIM FOR RELIEF
(FALSE STATEMENTS – 31 U.S.C. §3729(a)(1)(B))

138. The allegations of all paragraphs in this Complaint are incorporated by reference.

139. In performing the acts described above, the Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly made, used, and/or caused to be made or used, false records or statements material to false or

fraudulent claims paid or approved by Medicare, Medicaid, and TRICARE, in violation of 31 U.S.C. §3729(a)(1)(B).

140. As a result of the Defendants' fraudulent conduct, the United States government has been damaged in amounts to be determined at trial.

141. Additionally, the United States is entitled to penalties of up to $11,000 for each and every violation of 31 U.S.C. §3729(a)(1)(B)) by the Defendants. However, civil penalties under 31 U.S.C. §3729(a) shall be up to $21,563 per violation for penalties assessed after August 1, 2016, where the FCA violations occurred after November 2, 2015.

THIRD CLAIM FOR RELIEF
(FALSE CLAIMS – N.C. Gen. Stat. §1-607(a)(1))

142. The allegations of all paragraphs in this Complaint are incorporated by reference.

143. In performing the acts described above, the Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly presented, and/or caused to be presented, false or fraudulent claims for payment or approval under the North Carolina Medicaid program and/or other state health care programs, in violation of N.C. Gen. Stat. §1-607(a)(1).

144. As a direct result of the Defendants' conduct, the State of North Carolina has been damaged in amounts to be determined at trial.

145. Additionally, the State of North Carolina is entitled to penalties of up to $11,000 for each and every violation of N.C. Gen. Stat. §1-607(a)(1) by the Defendants.

FOURTH CLAIM FOR RELIEF
(FALSE STATEMENTS – N.C. Gen. Stat. §1-607(a)(2))

146. The allegations of all paragraphs in this Complaint are incorporated by reference.

147. In performing the acts described above, the Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly made, used, or caused to be made or used, false records or statements material to a false or fraudulent claim under the North Carolina Medicaid program and/or other state health care programs, in violation of N.C. Gen. Stat. §1-607(a)(2).

148. As a direct result of the Defendants' fraudulent conduct, the State of North Carolina has been damaged in amounts to be determined at trial.

149. Additionally, the State of North Carolina is entitled to penalties of up to $11,000 for each and every violation of N.C. Gen. Stat. §1-607(a)(2)) by the Defendants.

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of himself, the United States Government, and the State of North Carolina, prays as follows:

1. That for violations of the federal False Claims Act, 31 U.S.C. §3729, *et seq.*, this Court enter Judgment against the Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of the Defendants' actions, plus a civil penalty of $11,000 for each action in violation of 31 U.S.C. §3729, and $21,563 per violation for penalties assessed after August 1, 2016, where the FCA violations occurred after November 2, 2015;

2. That for violations of the North Carolina False Claims Act, N.C. Gen. Stat. §1-605 *et seq.*, this Court enter Judgment against Defendant in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendant's actions, plus a civil penalty of $11,000 for each action in violation of N.C. Gen. Stat. §1-607(a);

3. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. §3730(d) and N.C. Gen. Stat. §1-610, including the costs and expenses of this action and reasonable attorneys' fees;

4. That a trial by jury be held on all issues; and

5. That the United States Government, the State of North Carolina, and Relator, receive all relief, both in law and equity, to which they reasonably shall be entitled.

Respectfully Submitted,

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